ZAP NEUTRAL- sodium fluoride gel
Crosstex International Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active Ingredient:

Sodium Fluoride 2% (0.9% Fluoride Ion)

Purpose:

Anticaries Treatment.

Indications and Usage:

This is a prescription fluoride treatment gel used to help prevent dental decay.

Warnings:

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- This product contains a concentrated fluoride amount and is available by prescription only. It should be used under professional supervision.

Dosage and Administration:

Shake lightly before use. This is a four minute topical fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxsis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.

2. Instruct patient to bite down lightly but firmly four minutes.

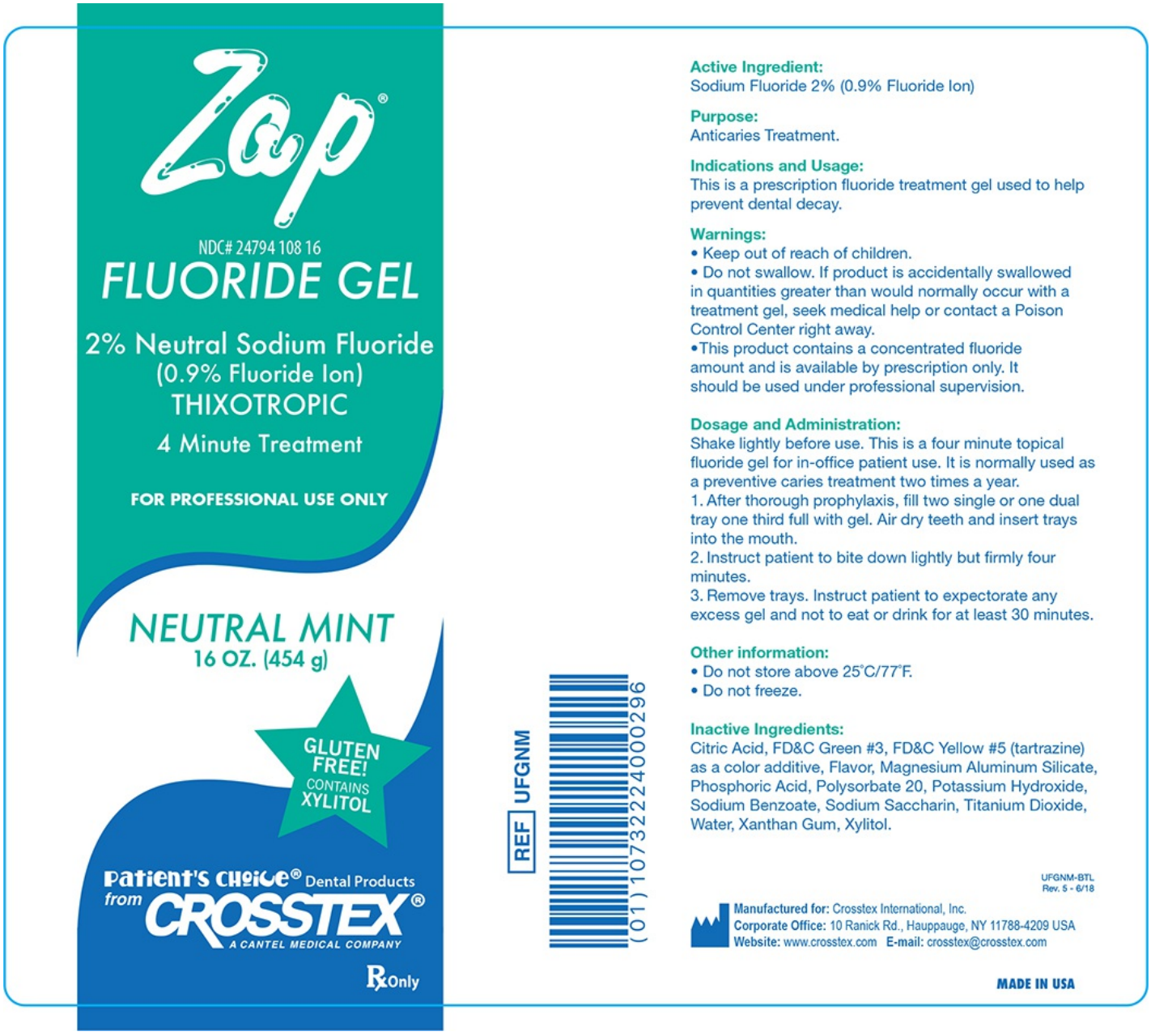
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

Other Information:

- Do not store above 25°C/77°F.
- Do not freeze.

Inactive Ingredients:

Citric Acid, FD&C Green #3, FD&C Yellow #5 (tartrazine) as a color additive, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Potassium Hydroxide, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.



ZAP NEUTRAL

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24794-108
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.086 g in 454 g

Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24794-108-16	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/14/2012	

Labeler - Crosstex International Inc. (057728685)

Revised: 1/2022 Crosstex International Inc.